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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,007	08/10/2001	Brian Eugene Baldwin	50012-00004	6430

7590

10/16/2003

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EXAMINER

NASH, BRIAN D

ART UNIT PAPER NUMBER

3721

DATE MAILED: 10/16/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/928,007

Applicant(s)

BALDWIN ET AL.

Examiner

Brian D-Nash

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-7,9-19 and 79-106 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7,9-19,79-88 and 91-106 is/are rejected.
- 7) ☒ Claim(s) 89 and 90 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 August 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 11.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

**DETAILED ACTION**

1. This action is in response to applicant's amendment received 11 August 2003. Applicant has amended claims 1 and 18, cancelled claims 20-32, and added new claims 79-106. The pending claims are now 1-7, 9-19, and 79-106.

***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-7, 9-16, and 79-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 3,823,818 to Shaw. Shaw discloses the invention substantially as claimed including a plurality of cylindrical bodies attached via a flexible belt and having a predetermined orientation and spacing with at least one end of the cylindrical body accessible; the belt having opposing layers that can be adhesively joined and with the cylindrical body in between (see Shaw, Figs. 1,3). However, Shaw does not show syringe bodies attached to the flexible web.

It would have been an obvious matter of design choice to substitute a plurality of syringe bodies in place of the molded performs, since the applicant has not disclosed that the specific type of cylindrical body used solves any stated problem and it appears that the invention would perform equally well with the syringe bodies attached to the flexible web.

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Regarding claims 16, 79, and 83-84 claiming the belt to be substantially transparent or opaque, Shaw discloses that the webs (40) used may be of any suitable material. It would have been an obvious matter of design choice to make the webs opaque and/or transparent in order to better suit the needs of the printed indicia and/or labeling since the applicant has not disclosed that making the webs either transparent or opaque solves any stated problem and it appears that the claimed invention would perform equally well with either.

Regarding claims 80-82 and 85 claiming portions of the belt being provided for printing, Shaw discloses ample sections of the belt provided on which printed indicia and/or labels could be placed. Recitation with respect to the manner in which a claimed apparatus is intended to be used does not differentiate it from the prior art apparatus satisfying the claimed structural limitations.

4. Claims 17-19 and 91-106 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 3,823,818 to Shaw in view of US 5,884,457 to Ortiz et al. As discussed above in paragraph 3 of this office action, Shaw discloses the invention substantially as claimed, but does not specifically disclose syringe bodies containing a sterile volume and wherein the syringes have a removable cap and fluid port with outer flange on the dispensing end and a slidably disposed plunger on the opposing end (see Ortiz, Figs. 2-4). However, Ortiz teaches an apparatus using a plurality of syringes containing a sterile volume and wherein the syringes have a removable cap and fluid port with outer flange on the dispensing end and a slidably disposed plunger on the opposing end for the purpose of producing a plurality of prefilled syringes with removable caps.

In view of Ortiz, it would have been obvious to one having ordinary skill in the art to have used the syringe bodies having a removable cap and fluid port with outer flange on the

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dispensing end and a slidably disposed plunger on the opposing end in place of the molding preforms for the purpose of producing a plurality of prefilled syringe bodies.

5. Claims 87 and 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 3,823,818 to Shaw in view of US 5,651,775 to Walker et al. As discussed above in paragraph 3 of this office action, Shaw discloses the invention substantially as claimed, but does not show sheet labels affixed to the belt between the syringe bodies wherein the sheet labels contain printed indicia with content-related information. Walker et al teach the use of preprinted labels, having, content-related information, affixed to the flap sections of syringe barrels.

It would have been obvious to one having ordinary skill at the time of the invention to have incorporated the idea of affixing labels having content-related information to the belt holding the syringe bodies for the purpose of providing drug identification indicia and drug preparation information.

#### ***Allowable Subject Matter***

6. Claims 89 and 90 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Response to Arguments***

7. Applicant's arguments filed 15 August 2003 have been fully considered but they are not persuasive. Regarding claims 1-7 and 9-16, applicant contends, *inter alia*, that Shaw does not obviate the claimed invention. Examiner acknowledges applicant's position; however, a

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reference and/or references is/are deemed to properly obviate a claim when the prior art reference (or references when combined) teach or suggest all the claim limitations. In this instance, Shaw clearly shows a plurality of cylindrical bodies fixedly attached to a belt in a predetermined orientation. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the problem to be solved by the applicant's invention is to provide a method, system and apparatus for enhanced syringe handling. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to have incorporated the method, system and apparatus of Shaw with syringe bodies in order to make the handling and preparation of syringe bodies more efficient.

8. Regarding claims 17-19, applicant argues that the examiner's conclusion of obviousness is based upon improper hindsight reasoning. It must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). In this instance, Shaw lacks the specific structural limitation of the syringe body. Ortiz et al teach an automated apparatus using syringe bodies having these

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limitations and therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to have used the teachings of Ortiz et al in order to use such specific syringe bodies in an automated process.

For the reasons above, the grounds for rejection are deemed proper.

9. The declarations under 37 CFR 1.132 filed 11 August 2003 are insufficient to overcome the rejection of claim 1 based upon Shaw as set forth in the last Office action because: although the declarations demonstrate Brian E. Baldwin and Randall W. Smith to be ones of ordinary skill in the art the declarations fail to provide support as to why it would not be obvious to one having ordinary skill in the art, at the time of the invention, to incorporate syringe bodies with the disclosed apparatus of Shaw in order to produce the claimed invention.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness. It is well known in the art to use teachings of similar methods and apparatuses in manufacturing as a means to improve and/or increase the efficiency of existing techniques. Shaw clearly shows an automated apparatus for handling a plurality of cylindrical bodies fixedly attached to a belt in a predetermined orientation and the substitution of syringe bodies for the thermoplastic performs would have been obvious.

### ***Conclusion***

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

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MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Nash whose telephone number is (703) 305-4959. The examiner can normally be reached on Monday – Thursday from 8 a.m. to 5 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi I. Rada can be reached at 703 308-2187.

The fax number for this Group is: 703-872-9306

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1148.

Brian D. Nash  
14 October 2003

A handwritten signature in black ink, appearing to read 'Rinaldi I. Rada', with a long horizontal line extending to the right.

Rinaldi I. Rada  
Supervisory Patent Examiner  
Group 3700